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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,296	09/19/2006	Jacques Georges Denis Simon	19790-004US1 CER03-0010	1650
26191 7590 04/01/2009 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER PRATT, HELEN F	
			ART UNIT 1794	PAPER NUMBER
			NOTIFICATION DATE 04/01/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/561,296	Applicant(s) SIMON ET AL.	
	Examiner Helen F. Pratt	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12-20-05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 14, 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 12 and 14 are indefinite in the use of the phrase “up to” which reads on zero, meaning that there is no resistant starch in the compositions. Claim 29 provides for the use of a sterilized resistant starch composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 29 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 29 is also indefinite in the use of the phrase “including”. Proper Markush language is “from the group consisting of digestive disorder...”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-27, 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giddy et al. in view of Moses (3,386,889).

Giddey et al. disclose a method of mixing a fatty material together with a starch product and sterilizing the mixture, then adding sterilized water to make an emulsion (abstract). The oil can be various oils such as peanut sunflower, corn (claims 5 and 6)(col. 3, lines 25-30). Sterilizing can be at temperatures at from 100 to 150 degrees (claim 30). Cooling the starch is an obvious step, and within the skill of the ordinary worker.

Claims 1, 5, 6, 16, 30 differ from the reference in the use of resistant starch. However, the reference discloses that almost any type of starch can be used (col. 3, lines 30-36). Also, Moses et al. disclose that it is known to sterilize resistant starches and dextrans at boiling temperatures (col. 1, lines 59-66 and col. 6, lines 15-24, col. 4, lines 1-6). Therefore, it would have been obvious to sterilize yet another starch for the known function of making the product free of bacteria, and to substitute the resistant starch of Moses for the starches of the reference in order to make a sterilized resistant starch.

It would have been within the skill of the ordinary worker to immediately cool the sterilized starch, as further cooking could gelatinize the starch as in claim 2. Therefore, it would have been obvious to quickly cool the sterilized starch in the process of the combined references.

Claim 3 further requires the use of 25% resistant starch. The particular amount is seen as being within the skill of the ordinary worker depending on how much of the product would be used for metabolism. Therefore, it would have been obvious to use particular amounts of starch in the claimed composition.

Maltodextrins are considered to be included in the cited dextrans as in claim 4 of the reference to Moses et al (col. 1, lines 64, 65). Therefore, it would have been obvious to use a particular form of dextrin in the claimed composition.

Claims 7 and 8 further require particular amounts of resistant R) starch to oil. The reference to Giddy et al. disclose various ratios of such, which are within the claimed range. Therefore, it would have been obvious to use known ranges in the process of the combined references.

Emulsifiers are disclosed by Giddy et al. as in claim 9 in col. 5, lines 15-16. The emulsifier is added after the flour and oil are mixed. However, no patentable distinction is seen at this time in adding the emulsifier before heating as the emulsifier performs its known function, when added at either point. Therefore, it would have been obvious to add the emulsifier before heating to perform its known function of being present if water were added to the composition so that it could be emulsified.

The product has been shown as above as in claim 10. Claim 10 is also a product by process claim. The fact that the procedures of the reference are different than that of applicant is not a sufficient reason for allowing the product-by-process claims since the patentability of such claims is based upon the product formed and not the method by which it was produced. See *In re Thorpe* 227 USPQ 964. The burden is upon applicant to submit objective evidence to support their position as to the product-by-process claims. See *Ex parte Jungfer* 18 USPQ 2D 1796.

The composition as shown by *Giddey et al.* in view of *Moses et al.* can certainly be used in a feed composition as it is edible, and in any composition requiring a sterilized starch as in claim 11, particularly as the specification discloses that resistant starches are used in such a manner.

Mosses et al. disclose as in claim 12, in particular, the use of a resistant starch as an ingredient in a bacteria medium (col. 1, lines 64-68). Other ingredients such as carbohydrates, minerals such as potassium and water are disclosed as in claim 13 by *Moses et al.* in col. 4, lines 48-70. Therefore, it would have been obvious to use the product of the combined references in a medium requiring starch and it would have been obvious to add other ingredients to a starch composition as claimed.

The protein source as in claim 14 is a well known and it would have been obvious to use known sources of protein in the claimed compositions.

As the process for making the composition has been shown above as in claim 15, it would have been within the skill of the ordinary worker to use it for enteral

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purposes, if a resistant starch were required. Therefore, it would have been obvious to use the treated R. starch wherever other starches are used.

Claim 17 further requires that the steps are carried out simultaneously. Certainly, this step would have been within the skill of the ordinary worker, since both ingredients should be kept sterile.

Aseptic packaging as in claim 18 is well known, therefore, it would have been obvious to use such to make a sterile product.

The limitations of claims 19--27 have been disclosed above and are obvious for those reasons.

Giddey et al. disclose the use of only starch as in claims 31 and 32 (col. 5, lines 15-20). As above, it would have been obvious to use resistant starch in place of the starch of Giddey et al. as disclosed by Moses et al., since Moses et al. disclose that it is known to sterilize a resistant starch and Giddey et al. disclose that various starches can be sterilized with his method.

Claims 10-15, 28 , 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giddey et al. in view of Mosses et al. as applied to claims 1-27, 30-32 above, and further in view of Laughlin et al. (5,470,839).

Laughlin et al disclose a composition containing carbohydrate resistant starch and protein as in claims 10-13, 15. The R starch of the reference is a high amylase starch which is resistant to digestion (col. 4, lines 35-48, col. 5, lines 41-50). Enteral diets are routinely sterilized since they are often given to sick people. A resistant starch as defined by applicants' specification is one which is resistant to digestion. The

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protein source as in claim 14 is a well known, and it would have been obvious to use known sources of protein in the claimed compositions. Therefore, it would have been obvious to use the R. starch as disclosed by Laughlin in a nutritional composition in the composition of the combined references.

Resistant starch has been disclosed above by Laughlin et al. in claims 28 and 29 in the use of high amylase starch in the treatment of diabetes. It would have been obvious to sterilize the starch as disclosed by Giddey et al. in view of Moses et al., since it is known to sterilize other starches in oil as disclosed by the references and to use it in a medicament as shown by Laughlin et al. as in an enteral diet.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Keith Hendricks, can be reached on 571-272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

/Helen F. Pratt/

Primary Examiner, Art Unit 1794 3-26-09